

GCRC/OCR Clinical Research Seminar

Successful Subject Recruitment Strategies

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Presenters:

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Project Manager, Clinical Epidemiology Research and Training Unit

Mary-Tara Roth, RN, MSN, MPH

Research Subject Advocate, GCRC

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Professor of Emergency Medicine

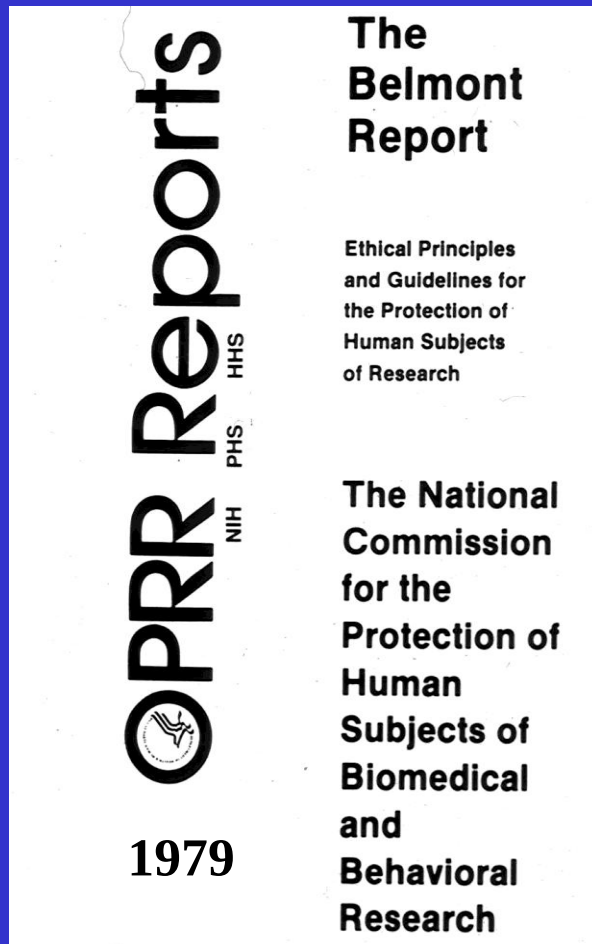
Moderator:

Richard Saitz MD, MPH

Associate Director, Office of Clinical Research

Thanks to Susan Fish, PharmD, MPH

BELMONT REPORT

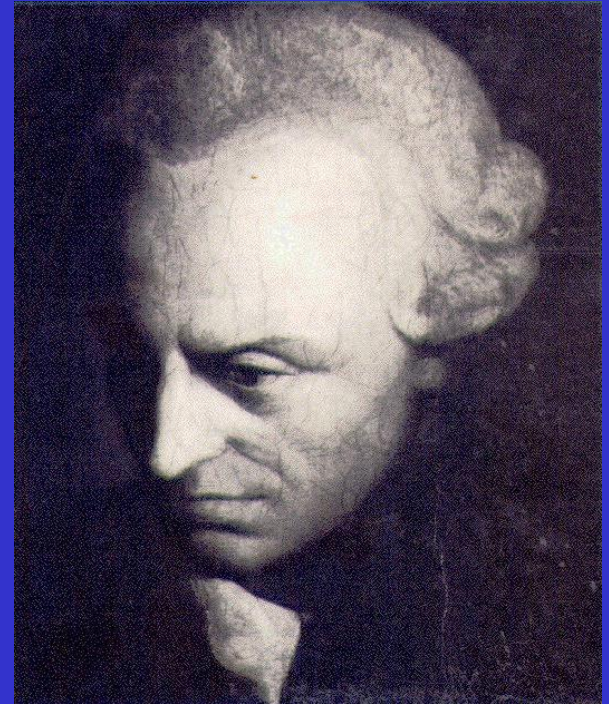


3 Ethical Principles

- Respect for Persons
- Beneficence
- Justice

Respect for Persons

- Treat individuals as autonomous agents
- Do not use people as a means to an end
- Allow people to choose for themselves
- Give extra protection to those with limited autonomy



Voluntary Choice

- Requires “truth in advertising”
- Requires adequate information with which to make the choice
- Requires understanding and trust
- Requires empowerment

Justice

- Treat people fairly
- Fair sharing of burdens and benefits of research
- Distinguish procedural justice from distributive justice



CRITERIA FOR IRB APPROVAL

45 CFR 46.111

21 CFR 56.111

- Minimized risks
- Reasonable risk/benefit ratio
- **Equitable subject selection**
- **Informed consent process**
- Informed consent documented
- Data monitored for safety
- Confidentiality/privacy maintained
- **Vulnerable populations protected**

IRB Review

- Needed for any recruitment material that will be seen by research subjects and any recruitment plan (e.g. asking clinicians to refer patients to the study).

What should an ad include?

1. Contact Information
2. Condition studied or purpose
3. Criteria for eligibility
4. ?Benefits and Risks
5. Commitment required
6. Compensation

Ad do's and Don't's include?

Don't	Do
Treatment	Research study
New drug/treatment	Investigational/research drug
exciting, cutting edge"	Purpose of research
"Free" "\$\$\$"	You will be paid X for your time
"Patient"	Subject or Participant

Thanks to Erin Larson Reilly MPH

Websites: No different

- **When Is IRB Review of Clinical Trial Websites Required?**
 - When information posted on a clinical trial website goes beyond directory listings with basic descriptive information
 - Basic descriptive information includes:
 - study title
 - purpose of the study
 - protocol summary
 - basic eligibility criteria
 - study site location(s), and
 - how to contact the study site for further information.

Thanks to Mary Banks RN, BS, BSN: from OHRP Sept 20, 2005 guidance at <http://www.hhs.gov/ohrp/policy/clinicaltrials.html>

Websites

- IRB needs to review:
 - Descriptions of clinical trial risks and potential benefits (must be balanced and fair), or solicitation of identifiable information.
 - Same review as other recruitment materials

Contacting Subjects

- From clinical data
- From publicly observable activities
- From publicly available lists

Recruitment of Research Subjects

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